

REMARKS/ARGUMENTS

By this Response, Claims 1-70 are currently pending.

The Examiner has rejected Claims 1, 9, 38, 44 and 45 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. 2002/0193746 (Chevallier) and/or U.S. Patent No. 6,319,233 (Jansen) in view of U.S. Patent No. 7,097,634 (Gilbert). In particular, the Examiner asserts that Chevallier (as well as Jansen) discloses all the elements of Claims 1, 9, 38, 44 and 45 except for the feature of the needle cannula being disposed within the shield prior to activation of the device. To make up for that deficiency, the Examiner cites Gilbert (viz., col. 1, lines 20-50) as disclosing that feature and that it would have been obvious to one of ordinary skill in the art to modify the syringe of Chavallier (or of Jansen) as disclosed by Gilbert to arrive at the claimed inventions.

Applicants respectfully disagree for the following reasons: Gilbert discloses an automatic injection device that provides a bias mechanism 70 for driving a syringe cartridge 20 and its associated needle 22 back from an extended position to a retracted position (Gilbert, col. 5, lines 8-10). The needle 22 is disposed in the body of the injection device before use. When the device is used, the syringe cartridge 20/needle 22 are pushed forward and a dose delivered using the motive force of a coil spring (52 in Fig. 1). This pushes the syringe 24 and hence the needle 22 forwards such that the needle 22 projects from the distal end 9 of the injector, and also delivers the dose. Once the dose has been delivered, a second spring coil spring 21 exerts a bias force sufficient to return a portion of the needle 22 into the body of the injector 10. Fig. 6 of Gilbert shows the tip of the needle still exposed beyond the distal end 9 after the bias mechanism 70 has been activated.

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This type of *retraction* injection device is well-known, as discussed in Gilbert, col. 1, lines 20-50 (which is also cited by the Examiner). However, the device of Chevallier uses inner and outer concentric sheaths that cooperate to provide a safety cover for the needle once the drug has been delivered. There is no needle/syringe *retraction* occurring in the Chevallier device (nor in the device of the present invention) as there is in the Gilbert device. Thus, Applicants submit that there is no suggestion to combine the teachings and suggestions of Chevallier and Gilbert as advanced by the Examiner, except from using Applicants' invention as a template through hindsight reconstruction of the pending claims. Furthermore, even if one skilled in the art were to combine Chevallier and Gilbert, the result would still be an exposed needle after the device activation, as shown by Fig. 6 of Gilbert. Applicants therefore respectfully submit that the invention of Claims 1, 9, 38, 44 and 45 are patentable over any proposed combination of Chevallier and Gilbert and respectfully request that the §103(a) rejection based thereon be removed.

With regard to the rejection of Claims 1, 9, 38, 44 and 45 under 35 U.S.C. §103(a) based on Jansen and Gilbert, Applicants also respectfully disagree for the following reasons: The injection devices of Jansen require user intervention in order to deploy their respective shields after injection. Again, as in Chevallier, there is no needle/syringe *retraction* occurring in the Jansen embodiments (nor in the device of the present invention) as there is in the Gilbert device. Thus, Applicants submit that there is no suggestion to combine the teachings and suggestions of Jansen and Gilbert as advanced by the Examiner, except from using Applicants' invention as a template through hindsight reconstruction of the pending claims. Furthermore, even if one skilled in the art were to combine Jansen and Gilbert, the result would still be an exposed needle

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after the device activation, as shown by Fig. 6 of Gilbert. Applicants therefore respectfully submit that the invention of Claims 1, 9, 38, 44 and 45 are patentable over any proposed combination of Jansen and Gilbert and respectfully request that the §103(a) rejection based thereon be removed.

The Examiner has rejected Claims 2, 3-7, 8, 10-15, 35-37, 46-48, 61, 63-64, 70, 19-21, 50-52 and 58-59 under 35 U.S.C. §103(a) as being unpatentable over Chevallier and/or Jansen in view of U.S. Patent Publication No. 2003/01005430 (Lavi, et al.) and/or U.S. Patent No. 5,599,309 (Marshall) and further in view of Gilbert¹.

Applicants respectfully disagree for the following reasons.

Claim 2 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, the Examiner's assertion that "it would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the injection syringe of Chevallier as disclosed by Lavi and/or Marshall to make the safety shield injection syringe automated" changes the principle of operation of the primary reference Chevallier which is to drive the stopper, and dispense the medication, upon activation of the syringe (Chevallier, p.1, paragraph 0009). Such a proposed modification is not permitted under MPEP §§2143/VI and 2145/III. In addition, on page 7 of the Final Rejection, the Examiner states that the syringe, as disclosed by Gilbert, is automated. However, as stated previously, Gilbert is directed to the retraction of the syringe/needle, and does not even employ the use of a shield that is slidably coupled to the

¹ In rejecting Claims 16-18, 53-57, 60, 22-25, 39-42, 26, 28-31, 49, 65-66, 69, 27, 62, 32-34, 43, and 67-68 under §103(a), the Examiner asserts that because components are found in the cited art, this renders these particular claims as being obvious. One of the criteria of establishing a *prima facie* case of obviousness is that the prior art references must teach or suggest all of the claim limitations (MPEP §2143), *not just components* mentioned in the claims.

housing for covering the needle. Thus, although Gilbert may have an automated syringe/needle retraction, there is no teaching or suggestion of an automated shield deployment, as specified in Claim 1 from which Claim 2 depends. Thus, for all of these reasons, Applicants respectfully submit that Claim 2 is patentable over the art of record.

Claim 3 is dependent upon Claim 1 and is patentable for the same reasons. Furthermore, the Examiner's assertion citation of Figs. 6-9 of Marshall still does not render the invention of Claim 3 as being obvious for the following reasons. Fig. 6 forms a second embodiment of Marshall which appears to use the same nose 3 of the first embodiment (Figs.1-2). In that first embodiment, there appears to be no relative movement of the nose 3² with respect to the barrel 1. The third embodiment of Marshall shown in Figs. 7-12 uses a nose 42 which screws into the forward end of cylindrical portion 41 of a sloping shoulder 40 of barrel 31 that is also screwed onto the forward end of the body 31³. See Marshall, col. 4, lines 14-19. Thus, there is no "movement of any shield with the respect to the housing" as specified in Claim 3. As a result, even if one skilled in the art were to combine Chevallier with Marshall, this would still not render the invention obvious. In addition, on page 7 of the Final Rejection, the Examiner states that Jenson discloses a moving shield. However, that assertion still does not make up for the deficiencies in Marshall, if that reference is being cited in combination with Jansen. To that end, Applicants respectfully submit that for all of these reasons, Claim 3 is patentable over the art of record and respectfully request that the §103(a) rejection be withdrawn.

² Marshall, col. 2, lines 52-54 specifies that "a nose piece 3 is fitted into the mouth of the barrel 1 and provides a shield and a guide for a capsule 4 with a needle 5." The term "fitted" appears to support a "fixed" relationship between the nose 3 and barrel 1.

³ It should be also noted that with respect to this third embodiment of Marshall, Fig. 9 depicts the "after use" state

Claim 4 is dependent upon Claim 3 and is patentable for the same reasons.

Claim 5 is dependent upon Claim 3 and is patentable for the same reasons.

Claim 6 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 7 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 8 is dependent upon Claim 1 and is patentable for the same reasons.

Claim 10 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 11 is dependent upon Claim 10 and is patentable for the same reasons.

Claim 12 is dependent upon Claim 10 and is patentable for the same reasons.

Claim 13 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 14 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 15 is dependent upon Claim 14 and is patentable for the same reasons.

Claim 16 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 17 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 18 is dependent upon Claim 17 and is patentable for the same reasons.

Claim 19 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 20 is dependent upon Claim 19 and is patentable for the same reasons.

Claim 21 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 22 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 23 is dependent upon Claim 22 and is patentable for the same reasons.

Claim 24 is dependent upon Claim 22 and is patentable for the same reasons.

of the injector which clearly shows an exposed needle 36, in contravention to the limitations of Claim 1 of the present invention.

Claim 25 is dependent upon Claim 23 and is patentable for the same reasons.

Claim 26 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 27 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 28 is dependent upon Claim 9 and is patentable for the same reasons.

Claim 29 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 30 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 31 is dependent upon Claim 21 and is patentable for the same reasons.

Claim 32 is dependent upon Claim 28 and is patentable for the same reasons

Claim 33 is dependent upon Claim 32 and is patentable for the same reasons.

Claim 34 is dependent upon Claim 32 and is patentable for the same reasons.

Claim 35 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 36 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 37 is dependent upon Claim 33 and is patentable for the same reasons.

Claim 39 is dependent upon Claim 28 and is patentable for the same reasons.

Claim 40 is dependent upon Claim 39 and is patentable for the same reasons.

Claim 41 is dependent upon Claim 39 and is patentable for the same reasons

Claim 42 is dependent upon Claim 39 and is patentable for the same reasons.

Claim 43 is dependent upon Claim 38 and is patentable for the same reasons.

Claim 46 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 47 is dependent upon Claim 46 and is patentable for the same reasons.

Claim 48 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 49 is dependent upon Claim 48 and is patentable for the same reasons.

Claim 50 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 51 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 52 is dependent upon Claim 51 and is patentable for the same reasons.

Claim 53 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 54 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 55 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 56 is dependent upon Claim 55 and is patentable for the same reasons.

Claim 57 is dependent upon Claim 55 and is patentable for the same reasons.

Claim 58 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 59 is dependent upon Claim 58 and is patentable for the same reasons.

Claim 60 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 61 is dependent upon Claim 60 and is patentable for the same reasons.

Claim 62 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 63 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 64 is dependent upon Claim 63 and is patentable for the same reasons.

Claim 65 is dependent upon Claim 63 and is patentable for the same reasons.

Claim 66 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 67 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 68 is dependent upon Claim 67 and is patentable for the same reasons.

Claim 69 is dependent upon Claim 45 and is patentable for the same reasons.

Claim 70 is dependent upon Claim 45 and is patentable for the same reasons.

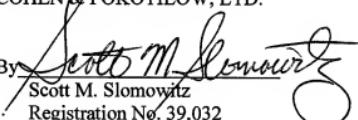
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Thus, Applicants respectfully submit that Claims 1-70 are now in condition for allowance. Accordingly, prompt and favorable examination on the merits is respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for initial examination and allowance, the Examiner is invited to contact Applicant's undersigned attorney at the telephone number listed below.

Respectfully submitted,

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